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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS S. WILSON and
DUNCAN J. MAITLAND

Appeal 2010-001890
Application 10/801,355
Technology Center 3700

Before MICHAEL W. O'NEILL, GAY ANN SPAHN and
MICHAEL L. HOELTER, *Administrative Patent Judges*.

HOELTER, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

This is a decision on appeal under 35 U.S.C. § 134(a), from the final rejection of claims 1-56. The real party in interest is Lawrence Livermore National Security, LLC. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

References Relied on by the Examiner

Kamiya	US 5,192,301	Mar. 9, 1993
Picha	US 5,207,709	May 4, 1993
Linden	US 5,634,936	Jun. 3, 1997
Bleys	US 6,034,149	Mar. 7, 2000
Maitland	US 2002/0095169 A1	Jul. 18, 2002
Porter	US 2002/0165582 A1	Nov. 7, 2002

The Claimed Subject Matter

The claimed subject matter is directed to a method and apparatus for delivering shape memory foam inside a body to occlude a physical anomaly or aneurysm. Independent claim 1 is illustrative of the claims on appeal and is reproduced below:

> 1. An apparatus for endovascular therapy by occluding a physical anomaly, said anomaly having an interior, comprising:
>
> a shape memory material body for positioning in the interior of the physical anomaly, wherein said shape memory material body comprises a shape memory polymer foam;
>
> a delivery system for delivering said shape memory material body that comprises a shape memory polymer foam into the interior of the physical anomaly; and
>
> a system for providing said shape memory material body that comprises a shape memory polymer foam with a primary shape for occluding the physical anomaly and a secondary shape for being delivered into the interior of the physical anomaly.

The Rejections on Appeal

1. Claims 1, 3, 4, 6-15, 21-23, 25-37, 43 and 44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland and Bleys (Ans. 3).

2. Claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47 and 49 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya and Bleys (Ans. 5).

3. Claims 2 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland, Bleys, and Picha (Ans. 6).

4. Claims 2, 24 and 46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya, Bleys, and Picha (Ans. 7).

5. Claim 5 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya, Bleys, and Linden (Ans. 7).

6. Claims 17-20 and 39-42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over either Kamiya or Maitland together with Bleys and Porter (Ans. 8).

7. Claims 48 and 50-52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya, Bleys, and Maitland (Ans. 9).

8. Claims 53-56 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamiya, Bleys, and Porter (Ans. 9).

9. Claims 16 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Maitland (Ans. 10).

ISSUE

Would one of ordinary skill in the art have had reason to deliver a shape memory foam to the interior of a physical anomaly or aneurysm to occlude the anomaly or aneurysm when it was known that a shape memory polymer can close a body defect and that foams having shape memory properties are useful in areas where contact with a human body is required?

ANALYSIS

Rejections 1, 3 and 9: Maitland does not Teach or Suggest Delivering a Shape Memory Material to the Interior of an Anomaly for Occluding the Anomaly.

The Examiner's rejections based on Maitland as the sole primary reference are not supported by a preponderance of the evidence. Maitland teaches that a "catheter with a shape memory material is transported to the site of the matter to be removed," "[t]he shape memory material is passed through or around the matter," and afterwards, the shape memory material is expanded so that when the catheter and expanded shape memory material is withdrawn from the body, the blockage matter is also removed (Maitland ¶ [0018]). Appellants argue that Maitland does not employ a shape memory polymer to occlude a physical anomaly or aneurysm as claimed, but instead Maitland teaches "a method of removing matter from a vessel" (App. Br. 11-12, Reply Br. 3-4, Maitland ¶ [0018]). Appellants also argue that Maitland is not inserted within the interior of an anomaly or an aneurysm, nor does Maitland suggest leaving shape memory material behind after the surgical procedure is completed to occlude or block off an anomaly or aneurysm (App. Br. 12, Reply Br. 3-6). The Examiner has not indicated how Maitland's shape memory material might be capable of being inserted into and occlude a physical anomaly in view of Maitland's different medical procedure of using a shape memory material to remove a clot from a blood vessel. For these reasons, we do not sustain the Examiner's rejection of those claims that are rejected based on Maitland as the sole primary reference for teaching the occlusion of an anomaly or an aneurysm.

Rejection 2: The Subject Matter of Claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47 and 49 are unpatentable over Kamiya and Bleys.

Kamiya teaches a closing plug and a delivery system for closing a body defect percutaneously, one such defect being an "aneurysm" that is plugged by use "of a shape memory material" (Kamiya 1:11-18, 2:62). Kamiya teaches that "[t]he kind of shape memory polymer is not particularly limited in the present invention" and provides examples of polymers such as "polyurethane" (Kamiya 3:1-5). Bleys teaches that "[p]olyurethane foams having shape memory properties are known" and that flexible foams are "especially useful in areas where contact with a human body is required like in medical and hygienic applications" and for "drug release products" (Bleys 1:32-37, 6:46-55). The Examiner concluded that it would have been obvious to modify Kamiya with Bleys' shape memory foam because of the foam's biocompatibility and because of its medical advantages (Ans. 5, 12).

Appellants contend that "the Kamiya device would not be operative with the Bleys shape memory polymer foam," because Kamiya's plug is not solid but instead contains a through-hole for passage of a guide wire (App. Br. 22, 26, Reply Br. 7). Kamiya states that "the through-hole is so narrow that the closing plug is actually as effective as that without a hole" (Kamiya 4:39-41). Further, Kamiya teaches other embodiments that "do not need any passing through-hole, so they can completely close the defect" (Kamiya 8:62-64). Based on these teachings, Appellants' contention is not persuasive.

Appellants also dispute the shape and construction of Kamiya's plugs (App. Br. 22, 26-27, Reply Br. 7-10). Kamiya states that "a shape memory polymer is molded to a shape suitable for closing a defect in a body part" and discloses more than a dozen plug variations (Kamiya Figs. 1-25, 3:16-

18). Again based upon these teachings, Appellants' contentions are not persuasive.

Appellants contend that, unlike Kamiya's plug, "Appellants' foam would not retain the desired shape when 'the molded closing plug is then deformed to a decreased size suitable to insert easily into the body part'" (underlining added) (Reply Br. 9). This is contrary to Appellants' Specification which states that Appellants' shape memory material, after being inserted into an anomaly, is caused "to change to the larger primary shape for occluding the anomaly" (Spec. ¶ [008], *see also* ¶ [0015] "Shape-memory materials have the useful ability of being formable into a primary shape, being reformable into a stable secondary shape, and then being controllably actuated to recover their primary shape"). Thus, Appellants' contention that its foam would not retain the desired shape is not persuasive.

Appellants further allege that Kamiya's closing plug is "cooled" to fix the plug in place and that Appellants' foam would not retain the desired shape when "cooled" (Reply Br. 9). Kamiya teaches both cooling and heating to cause the shape memory material to change from its delivered secondary shape to its occluding primary shape (Kamiya 3:27-48). The rejected claims require a system that causes the shape memory polymer material to change from its delivery state to its occluding state (*see* independent claims 1, 23 and 45). Kamiya teaches such a system using heating or cooling. Hence, Appellants' contention is not persuasive.

Appellants also reproduce portions of the rejected claims stating that the cited references do not teach the claim limitations that are reproduced (App. Br. 22-25, Reply Br. 9-10). Our reviewing court has held that the Board reasonably interpreted Rule 41.37 to require more substantive

arguments in an appeal brief than a mere recitation of the claim elements and a naked assertion that the corresponding elements were not found in the prior art. *See In re Lovin*, 99 USPQ2d 1373 (Fed. Cir. 2011).

Appellants further contend that Kamiya's device flange "could not be made of a shape memory polymer foam" because the foam "would not operate as a flange" (App. Br. 22, 26-27, Reply Br. 7-8). We find that Appellants' argument is not supported by credible evidence because Appellants failed to set forth any affidavits or declarations in support of their contention. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

Kamiya specifically addresses plugging an aneurysm (Kamiya 1:11-18) and specifically teaches that the plug "is made of a shape memory polymer" (Kamiya 1:44-45), and that a shape memory polymer can be made of "polyurethane" (Kamiya 3:1-5). Bleys teaches that "[p]olyurethane foams having shape memory properties are known" (Bleys 1:32-33) and that flexible foams are "especially useful in areas where contact with a human body is required" (Bleys 6:49-51). Therefore, one skilled in the art would have known that a polyurethane foam shape memory material could have been "molded to a shape suitable for closing a defect in a body part" (Kamiya 3:16-26) and that such plug would have been suitable for Kamiya's closure plug which is "deformed during the insertion and can recover to its original shape when fixed in place" (Kamiya 8:67-68).

Based on the record presented, we are not persuaded by Appellants' arguments and we sustain the Examiner's rejection of claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47 and 49 as being unpatentable over Kamiya and Bleys.

Rejection 4: The Subject Matter of Dependent Claims 2, 24 and 46 are unpatentable over Kamiya and Bleys in view of Picha.

Dependent claims 2, 24 and 46 further require "a mean pore size between ten microns and fifty microns." Picha specifically teaches "implantable medical devices" consisting of a foam having "a pore size of 10 microns to 50 microns" to permit interaction with bodily fluids and to "induce blood vessel proximity and neovascularization" (Picha 1:5-6, 8:42-46). The Examiner relies on Picha for teaching the claimed pore size and combines Picha with Kamiya and Bleys "since Picha teaches that such pore sizes allows tissue ingrowth" (Ans. 7). Appellants contend that this combination "does not establish a *Prima Facie* case of obviousness," that it "fail[s] to teach most of Applicants' claim limitations," that there is no reason for this combination, and that there is no reasonable expectation of success with this combination (App. Br. 32-35, Reply Br. 12-13).

As per our reviewing court[1], the Examiner has established a prima facie case of obviousness by identifying the references relied upon (i.e., Kamiya, Bleys and Picha) that teach Appellants' claim limitations and by also providing a reason for the expected successful combination of these references (Ans. 7, 13). Appellants' recitation of claim elements and naked assertion that these "references fail to teach" Appellants' claim limitations (App. Br. 32-35) do not disprove the Examiner's conclusion and are not

[1] "[A]ll that is required of the office to meet its prima facie burden of production is to set forth the statutory basis of the rejection and the reference or references relied upon in a sufficiently articulate and informative manner as to meet the notice requirement of [35 U.S.C.] § 132." *In re Jung,* 637 F.3d 1356, 1363 (Fed. Cir. 2011).

persuasive. Accordingly, we sustain the Examiner's rejection of claims 2, 24 and 46 as being unpatentable over Kamiya, Bleys and Picha.

Rejection 5: The Subject Matter of Dependent Claim 5 is unpatentable over Kamiya and Bleys in view of Linden.

Claim 5 depends directly from claim 1 and further requires that the polyurethane shape memory polymer foam have "a ten percent solution of shape memory polymer in dimethyl sulfoxide." Linden teaches a plug that "relates generally to the closure of intravascular defects" (Linden 1:6-10). Linden specifically teaches "a solution of water and DMSO (dimethylsulfoxide)" and that this solution "at a specific pH would keep the polymer soft and contracted" for delivery inside a body (Linden 6:30-37). The Examiner combines Linden with Kamiya and Bleys stating that dissolving a polymer foam with DMSO as taught by Linden is "well known and can be used to keep the foam soft prior to deployment" (Ans. 7, *see also* 13). As regarding the claimed "ten percent solution," the Examiner states that "discovering an optimum value of a result effective variable, in this case the amount of polymer dissolved in the DMSO, involves only routine skill in the art" (Ans. 7-8, 13-14).

Appellants again contend that the Examiner has not established a prima facie case of obviousness, that the combination does not teach the limitations of claim 5, that there is no reason for this combination, and that there is no reasonable expectation of success with this combination (App. Br. 35-39, Reply Br. 13-14). "[O]ne skilled in the art is able to read a reference for all that it teaches and not limit a reference to its preferred embodiment. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Because Linden teaches the desire to keep the polymer foam soft and contracted for delivery purposes and because the

Examiner's reasoning that to provide a 10% solution of DMSO would be no more than routine skill in this art overcomes the Appellants' insufficiently substantiated contentions, we sustain the Examiner's rejection of claim 5 in view of Kamiya, Bleys and Linden.

Rejections 6 and 8: The Subject Matter of Dependent Claims 17-20, 39-42 and 53-56 are unpatentable over Kamiya and Bleys in view of Porter.

Dependent claims 17-20, 39-42 and 53-56 further require microparticles or nanoparticles that can convert RF radiation to heat. Porter teaches "delivering materials to the body to bulk tissue or fill voids," and more specifically, a prepolymer that contains "microbeads" that are "adapted to heating by at least one external field chosen from a electromagnetic field, radio waves, and an microwaves" [sic.] (Porter ¶¶ [0002] and [0018]). Porter teaches that microbeads are desirable "because the small magnetic particles are a point heat source and do not cause significant tissue damage around the vascular site" (Porter ¶ [0082]). The Examiner relies on the combination of Kamiya, Bleys and Porter due to Porter's teaching of "a convenient point heat source and the use of a shape memory foam with a higher transition temperature" (Ans. 8-10, 14). Appellants again contend that the Examiner has not established a prima facie case of obviousness, that the combination does not teach the limitations of these claims, that there is no reason for this combination, and that there is no reasonable expectation of success with this combination (App. Br. 39-44, 47-50). Appellants fail to provide persuasive evidence that microparticles or nanoparticles are used for any particular purpose, provide any advantage or solve a particular problem as compared to Porter's microbeads in order to outweigh the Examiner's burden of obviousness.

As above, a mere recitation of the claim elements and a naked assertion that the corresponding elements are not found in the prior art is insufficient (*see In re Lovin).* For similar reasons, we sustain the Examiner's rejection of claims 17-20, 39-42 and 53-56 as being unpatentable over Kamiya, Bleys and Porter. As the rejection of claims 17-20 and 39-42 has been sustained, we do not address the Examiner's alternate rejection of these claims over Maitland, Bleys and Porter.

Rejection 7: The Subject Matter of Dependent Claims 48 and 50-52 are unpatentable over Kamiya in view of Bleys and Maitland.

Claims 48 and 50-52 each depend directly from independent method claim 45 and further require, respectively, "delivering electromagnetic energy optically," "optical heating" and "using a laser and an optical fiber to transmit laser light" to the shape memory polymer. Kamiya specifically teaches that the closing plug "is inserted to the desired location in the body and is then warmed to above the shape recovery temperature to recover the original shape suitable for closing the body defect" (Kamiya 3:22-26). Maitland teaches that "the shape memory material can be heated using various systems" including "converting optical energy into thermal energy" (Maitland ¶ [0057]). More specifically, Maitland teaches that "[p]rior to the laser being turned on, the SMP 23 is closed around the diffusing chamber 24[.] After the laser is turned on, light energy transmitted through the optical fiber 25 will cause the SMP to open" (Maitland ¶ 0070]). The Examiner combines Maitland with Kamiya and Bleys stating that "Maitland discloses that it is old and well known in the art to use optical fibers and lasers to heat a shape memory polymer" and that "Maitland provides a heating method that does will not [sic] cause trauma to the surrounding tissue" (Ans. 9, 14). Appellants reiterate the argument that there is no prima

facie case of obviousness, provide a naked assertion that the combination does not teach the listed claim limitations, that there is no reason for this combination, and that there is no reasonable expectation of success with this combination (App. Br. 44-47, Reply Br. 14-16). Appellants also reiterate contentions previously addressed with respect to claim 45 *supra*. For reasons previously set forth, we sustain the Examiner's rejection of claims 48 and 50-52 as being unpatentable over Kamiya, Bleys and Maitland.

CONCLUSION OF LAW

One of ordinary skill in the art would have had reason to deliver a shape memory foam to the interior of a physical anomaly or aneurysm to occlude the anomaly or aneurysm when it was known that a shape memory polymer can close a body defect and that foams having shape memory properties are useful in areas where contact with a human body is required.

DECISION

1. The rejection of claims 1, 3, 4, 6-15, 21-23, 25-37, 43 and 44 under 35 U.S.C. § 103(a) as being unpatentable over Maitland and Bleys is reversed.
2. The rejection of claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47 and 49 under 35 U.S.C. § 103(a) as being unpatentable over Kamiya and Bleys is affirmed.
3. The rejection of claims 2 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Maitland, Bleys, and Picha is reversed.
4. The rejection of claims 2, 24 and 46 under 35 U.S.C. § 103(a) as being unpatentable over Kamiya, Bleys, and Picha is affirmed.

5. The rejection of claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Kamiya, Bleys, and Linden is affirmed.

6. The rejection of claims 17-20 and 39-42 under 35 U.S.C. § 103(a) as being unpatentable over either one of Kamiya or Maitland together with Bleys and Porter is affirmed.

7. The rejection of claims 48 and 50-52 under 35 U.S.C. § 103(a) as being unpatentable over Kamiya, Bleys, and Maitland is affirmed.

8. The rejection of claims 53-56 under 35 U.S.C. § 103(a) as being unpatentable over Kamiya, Bleys, and Porter is affirmed.

9. The rejection of claims 16 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Maitland is reversed.

In summary, the rejection of claims 4, 6, 8-16, 26 and 30-38 are reversed and the rejection of claims 1-3, 5, 7, 17-25, 27-29 and 39-56 are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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